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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,872	03/21/2006	Per Broberg	06275-502US1	3651
26164 7590 08/18/2009 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER				
KOSSON, ROSANNE				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
08/18/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary**Application No.**

10/572,872

Applicant(s)

BROBERG ET AL.

Examiner

Rosanne Kosson

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The amendment filed on June 5, 2009 has been received and entered. Claims 1 and 5 have been amended. Claims 2 and 7-15 have been canceled. No claims have been added. Accordingly, claims 1 and 3-6 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In view of Applicants' amendments to the claims, the objections in the previous Office action are withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because they are drawn to a "peptide fingerprint." It is unclear if a peptide fingerprint refers to a data set (a collection of the measurements of the molecular masses of polypeptide fragments) or to a set of polypeptide fragments themselves. Clarification and appropriate are required. Because an interpretation is needed to proceed with prosecution, however, the claims have been interpreted as being drawn to a data set, as such appears to be the intended meaning.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 3-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As noted above, the claims are drawn to a data set, a compilation of data, which does not correspond to a statutory class of invention. A data set is neither a product (a composition, machine or article or manufacture) nor a process. See MPEP § 2106. Appropriate correction is required.

Claim Rejections - 35 USC § 102

In view of Applicants' arguments and amendments to the claims, the rejections in the previous Office action are withdrawn.

Nevertheless, as discussed in the previous Office action, Mecham et al. ("Elastin degradation by matrix metalloproteinases," J Biol Chem 272(29):18071-18076, 1997) disclose a composition comprising the naturally occurring fragments of elastin that are produced by MMP12 proteolysis (see p. 18072, Materials and Methods; and pp. 18074 - 18075). HME (human macrophage metalloelastase) is an earlier name for MMP12. Mecham et al. do not disclose the number of elastin fragments that are produced. But, because elastin is digested by MMP12, inherently, all the naturally occurring fragments that correspond to all the molecular ions that would be detected by mass spectroscopy are produced and are present in the composition. Applicants have pointed out, however, that Mecham et al. used bovine elastin, while Applicants have used human elastin, and that the two proteins have substantially different amino acid sequences, which would yield different fragments.

As also previously discussed, Kucich et al. (WO 91/18290 A1) disclose a composition, human urine, comprising naturally occurring fragments of elastin, those produced in vivo by macrophage/neutrophil elastase (MMP12) (see pp. 4 and 7). Similarly to Mecham et al., Kucich

et al. do not disclose the number of elastin fragments that are produced. But, because elastin is digested by elastase/MMP12, inherently, all the naturally occurring fragments that correspond to all the molecular ions listed in Applicants' Tables 1 and 2 and identified by their molecular mass are produced and are present in the composition.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Mon.-Wed. 8:30-6:00, Fri. 8:30-2:00, Thurs. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2009-08-04

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656